

50 N.J.R. 1285(a)

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RULE ADOPTIONS

Reporter

50 N.J.R. 1285(a)

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> LAW AND PUBLIC SAFETY -- DIVISION OF CONSUMER AFFAIRS*

Agency

LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > STATE BOARD OF
MEDICAL EXAMINERS > BOARD OF PHARMACY

Administrative Code Citation

Jointly Adopted Amendment: N.J.A.C. 13:35-6.26

Jointly Adopted New Rule: N.J.A.C. 13:39-4.21A

Text

**Procedures for Physician Ordered Immunizations Performed by Licensed
Pharmacists; Requirements for Pharmacists to Administer Influenza
Vaccine to Patients Under 18 Years of Age**

Proposed: August 21, 2017, at 49 N.J.R. 2746(a).

Adopted: January 24, 2018, by the Board of Pharmacy, Richard Palombo,
R.Ph., President, and February 7, 2018, by the Board of Medical
Examiners, J. Paul Carniol, M.D., F.A.C.S., President.

Filed: April 25, 2018, as R.2018 d.115, **with non-substantial changes**
not requiring additional public notice and comment (see N.J.A.C. 1:30-
6.3).

Authority: N.J.S.A. 45:9-2 and 45:14-47.

Effective Date: May 21, 2018.

Expiration Date: April 3, 2025, N.J.A.C. 13:35;

November 3, 2024, N.J.A.C. 13:39.

Summary of Public Comments and Agency Responses:

The official comment period ended October 20, 2017. The Boards received comments from the following individual:

1. Jean Publiee.

1. COMMENT: The commenter recommends that N.J.A.C. 13:35-6.26 be amended to reference the 2017 Centers for Disease Control and Prevention (CDC) directive on injecting vaccines and information on cardiac rehabilitation from 2017. The commenter points out that the directive in the existing regulation is from 2007, and that information on cardiac rehabilitation is from 2005.

RESPONSE: Upon adoption, the Board of Medical Examiners has changed N.J.A.C. 13:35-6.26 to reference the most recent CDC guidelines for vaccine administrations, which are from 2015. The Board points out that one reference to the American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care in N.J.A.C. 13:35-6.26 was amended to reflect the most recent version of the guidelines, which is from 2010. The Board of Medical Examiners has changed N.J.A.C. 13:35-6.26 to correct a second reference to these guidelines.

2. COMMENT: The commenter recommends that N.J.A.C. 13:39-4.21A be amended to require pharmacists to provide parents with information on adverse effects of vaccines. Such information would include the lot number of the vaccine, that it was stored properly, the size of the dose, and the items that are part of the vaccine such as mercury, aluminum, or animal cells. This information would be signed by the pharmacist and kept as part of his or her records for seven years and a copy would be provided to the parent of the patient.

RESPONSE: The Board of Pharmacy points out that N.J.A.C. 13:39-4.21(g)3 already requires a pharmacist to inform patients or their representatives, in writing, as to the risks and benefits of a vaccine whenever the pharmacist administers a vaccine. The Board believes that this existing rule sufficiently addresses informing parents as to the risks of vaccines and that it is not necessary to change the rule as the commenter recommends.

Federal Standards Statement

A Federal standards analysis is not required because there are no Federal laws or standards applicable to the adopted amendments or new rule.

Regulations

Full text of the adoption follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks ***[thus]***):

[page=1286] CHAPTER 35

BOARD OF MEDICAL EXAMINERS

SUBCHAPTER 6. GENERAL RULES OF PRACTICE

13:35-6.26 Procedures for physician ordered immunizations performed by licensed pharmacists

(a) A New Jersey licensed physician may participate in an immunization program with a licensed pharmacist pursuant to N.J.S.A. 45:14-63 of the Pharmacy Practice Act, provided that the pharmacist is authorized to engage in such activities by the Board of Pharmacy pursuant to N.J.A.C. 13:39-4.21 and 4.21A, and provided the pharmacist administers vaccines and related emergency medications, which shall be limited to diphenhydramine and epinephrine, pursuant to:

1.-2. (No change.)

(b) A physician shall supervise a licensed pharmacist who is participating in an immunization program implemented pursuant to the physician's standing order. Supervision by the delegating physician shall be deemed adequate if the delegating physician:

1. Is responsible for formulating or approving a standing order, which shall include compliance with Centers for Disease Control and Prevention (CDC) guidelines for vaccine administrations, set forth in ***[Appendix D]* **Chapter 6, Vaccine Administration,**** of "Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book: Course Textbook)," updated ***[10th]* **13th**** edition, ***[February 2007]* **2015****. The CDC vaccine administration guidelines are incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, <http://www.cdc.gov/vaccines/pubs/pinkbook/appendix/index.html>. The standing order shall also include compliance with the American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (***[2005]* **2010****). The AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2010) are incorporated herein by reference, as amended and supplemented, and can be found at the AHA website, www.americanheart.org, specifically, http://circ.ahajournals.org/content/122/16_suppl_2/S250. The order shall also include procedures that shall be followed for the reporting

of adverse events, which shall include a requirement that adverse events are reported to the physician within 24 hours of notice of the event. The delegating physician shall annually review the order and the services provided to patients under the order;

2.-4. (No change.)

CHAPTER 39

STATE BOARD OF PHARMACY

SUBCHAPTER 4. PHARMACY PERMIT REQUIREMENTS

13:39-4.21A Requirements for pharmacists to administer influenza vaccine to patients under 18 years of age

(a) A licensed pharmacist must be authorized to administer vaccines and related emergency medications pursuant to and to comply with the requirements of N.J.A.C. 13:39-4.21.

(b) For a patient who is under 18 years of age, a pharmacist must obtain the written consent of the patient's parent or legal guardian.

(c) For a patient who is under 12 years of age, but is at least seven years of age, a pharmacist may administer the influenza vaccine only pursuant to a prescription by a licensed physician.

(d) A pharmacist shall not administer an influenza vaccine to a patient who is younger than seven years of age.

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